

**UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF TEXAS
SAN ANTONIO DIVISION**

WAVE NEUROSCIENCE, INC. a Delaware
Corporation,

Plaintiff,

vs.

BRAIN FREQUENCY LLC, a Texas Limited
Liability Company

Defendant.

Case No. 5:23-CV-00626-XR

Honorable: Xavier Rodriguez

PLAINTIFF'S OPENING CLAIM CONSTRUCTION BRIEF

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I. Introduction

Unlike many patent lawsuits that involve patents directed to incremental improvements in technology, the invention disclosed and claimed in each of patents-at-issue is truly ground breaking. Wave Neuroscience (“Wave”) is proud that its technology has resulted in a dramatic improvement in the health and well-being of numerous individuals previously suffering from not just the pain and reduced quality of life resulting from their malady, but also the stigma historically associated with brain disorders.

Because the underlying technology of the Wave patents involves treatment of neurological disorders in a manner that does not involve conventional treatments using psychiatry and/or medication, its acceptance by the medical profession and health insurance providers has impacted its adoption and availability to the patients. Fortunately, as evidence of the efficacy of Wave’s technology has continued to become more available and better understood, clinics throughout the United States of America and elsewhere are now rapidly increasing availability of this technology and its associated treatments to patients under license from Wave. Unfortunately, many companies, like Defendant, recognizing the potential financial benefits of operating a competing business infringing Wave’s patented technology, including the patents asserted here, are similarly beginning to proliferate, necessitating the current lawsuit.

The Parties have successfully reached agreement as to the proposed constructions for a number of claim terms/phrases at issue in this case. Given their importance to this case, Wave requests that the Court includes these agreed upon claim terms in its Claim Construction Order.

There remain, however, a number of claim terms that the parties dispute. For each of the disputed claim terms discussed herein, Wave presents a proposed construction that is not only consistent with what a person skilled in the relevant art would readily understand each such claim term to mean, but has ensured that each such proposed construction is in plain English so that a

jury will equally understand their meaning. In addition, each proposed claim construction is consistent with and supported by the intrinsic evidence, rather than an improper reliance on extrinsic evidence. Given their readily understood meaning and their reliance upon and support in the intrinsic evidence, the claim terms discussed herein warrant adoption by the Court.

II. Background

Wave is a recognized global-leader in developing personalized, non-invasive technology aimed at addressing neurological disorders and enhancing cognitive brain function through Transcranial Magnetic Stimulation (“TMS”). Wave’s technological advancements in the areas of testing and treatment of neurological disorders and in enhancing cognitive brain function using TMS are evidenced by its extensive patent and trademark portfolio and its collection of proprietary historical data of patient results and associated medical conditions.

Wave’s patented technology involves analyzing a patient’s electroencephalogram (“EEG”), electrocardiogram (“EKG”), or other biological metric results to derive insight into each patient’s brain health. Wave combines its proprietary algorithms with years of proprietary historical data to create an actionable cognitive treatment report. Doctors and clinics use Wave’s patented equipment and treatment protocols to treat patients to achieve long-lasting cognitive health.

The previous owner of the patents-in-suit, NeoSync, Inc. (“NeoSync”), was founded in 2008 as a clinical stage company. NeoSync helped pioneer personalized TMS for the treatment of major depressive disorder and other diseases of the central nervous system. Medical professionals acknowledged that synchronized TMS using EEG was a “new neuromodulation technique”, and confirmed the findings using NeoSync’s EEG Synchronized TMS (“N.E.S.T.”) device. Tache Dec. ¶ 2, Ex. A. On February 13, 2020, Wave acquired certain assets from NeoSync, including the patents-at-issue in this case, which enhanced Wave’s patent portfolio.

Wave's patented technology is being used by or in connection with numerous strategic partners, including the U.S. Department of Defense, Department of Veterans Affairs, Special Operations Care – Fund (SOC-F), Tomahawk Charitable Solutions, Texas A&M Institute for Bioscience and Technology, Ohio State University – Physical Medicine and Rehabilitation, Kerlan-Jobe Orthopedic Sports Medicine, Cedar-Sinai, University of Southern California Center for Neurorestoration, Enterhealth Ranch – Substance Abuse Treatment Center, and Warriors Heart – Addiction, Chemical Dependency & PTSD Treatment Center for Active Military, Veterans, and First Responders. Wave's products, services, and successful treatments practicing the patents at issue in this case have been featured on over 50 podcasts including The Broken Brain, Finding Center, The Joe Rogan Experience, Bulletproof Veteran, Military Veteran Dad, Vets First, and many more.

III. The Patents-in-Suit

Wave alleges that Defendants infringe Claims 1 and 9 of U.S. Patent No. 8,926,490 (Dkt. 029-04), Claims 1 and 3-7 of U.S. Patent No. 10,029,111 (Dkt. 029-02), Claims 1-4, 9-10, 12, and 20 of U.S. Patent No. 8,465,408 (Dkt. 029-03), and Claims 1-4, 8-9, and 11 of U.S. Patent No. 8,870,737 (Dkt. 029-05) (collectively “Asserted Patents”).

A. U.S. Patent No. 8,926,490 (the “’490 Patent”)

The ’490 Patent, entitled “SYSTEMS AND METHODS FOR DEPRESSION TREATMENT USING NEURO-EEG SYNCHRONIZATION THERAPY” issued on January 6, 2015. The ’490 Patent provides a system for a novel, inexpensive, and easy to use therapy for treating mental health disorders that gently tunes the brain, by using a magnetic field to move an intrinsic frequency within a specified EEG band, a Q-Factor of the intrinsic frequency within a specified EEG band, a coherence value within the specified EEG band, or an EEG phase of the specified EEG frequency of the subject toward a pre-selected or target intrinsic frequency within

the specified EEG band, Q-Factor of the intrinsic frequency within a specified EEG band, coherence value within the specified EEG band, or EEG phase of the specified EEG frequency, respectively.

B. U.S. Patent No. 10,029,111 (the “’111 Patent”)

The ’111 Patent, entitled “RTMS AT HARMONICS OF BIOLOGICAL SIGNALS” issued on July 24, 2018. The ’111 Patent provides a method for improving a physiological condition or a neuropsychiatric condition of a human mammal by subjecting the human to repetitive transcranial magnetic stimulation (“rTMS”) at the frequency or pulse rate of a non-EEG biological metric or harmonic or sub-harmonic of the metric, which is chosen based on the cognitive element or symptom that is targeted and designed to be closest to a desired EEG frequency.

C. U.S. Patent No. 8,465,408 (the “’408 Patent”)

The ’408 Patent, entitled “SYSTEMS AND METHODS FOR MODULATING THE ELECTRICAL ACTIVITY OF A BRAIN USING NEURO-EEG SYNCHRONIZATION THERAPY” issued on June 18, 2013. The ’408 Patent provides a method and a device for use in treating a number of mental health disorders, by gently tuning the brain and affects symptoms of the mental health disorders without the use of medication, using a magnetic field to influence an intrinsic frequency within a specified EEG band, a Q-Factor of the intrinsic frequency within a specified EEG band, a coherence value within the specified EEG band, or an EEG phase of the specified EEG frequency of the subject toward a pre-selected or target intrinsic frequency within the specified EEG band, Q-Factor of the intrinsic frequency within a specified EEG band, coherence value within the specified EEG band, or EEG phase of the specified EEG frequency, respectively.

D. U.S. Patent No. 8,870,737 (the “’737 Patent”)

The ’737 Patent, entitled “SYSTEMS AND METHODS FOR NEURO-EEG SYNCHRONIZATION THERAPY” issued on October 28, 2014. The ’737 Patent provides a method for a novel, inexpensive, and easy to use therapy for a number of mental health disorders that gently tunes the brain and affects mood, focus, and cognition of a subject, by using a magnetic field to influence an intrinsic frequency within a specified EEG band or a Q-Factor of the intrinsic frequency within a specified EEG band of the subject toward a pre-selected or target intrinsic frequency within the specified EEG band or Q-Factor of the intrinsic frequency within a specified EEG band, respectively.

IV. Level of Ordinary Skill in the Art

A person of ordinary skill in the art (“POSITA”) for the Asserted Patents is would be someone having knowledge and familiarity with electrophysiology and signal processing. Sufficient familiarity and experience with the subject matter of the Asserted Patents could be obtained by: (i) successfully completing a Bachelor’s degree in Electrical Engineering or Biomedical Engineering or similar discipline with classes or experience directed to electrophysiology and signal processing and TMS; (ii) a medical degree focusing on treatment of patients with brain disorders and experience with EEG and application of electrical or magnetic energy such as TMS; or (iii) at least three (3) years of experience in a job working with patients having brain disorders using treatment protocols involving TMS and EEG/electrophysiology.

At the time of the inventions, TMS was still a developing technology. Accordingly, there were limited regulatory approvals in place for the use of TMS in treating mental health disorders, nor was TMS in wide use in medical settings. Therefore, experience at that time would have consisted largely of concentrated research efforts into specific clinical conditions using predominant theories of TMS action at the time, which were the activation or inactivation of brain

tissue given high or low frequency applications of TMS. *See* Declaration of Marom Bikson (“Bikson Dec.”), ¶¶ 14-15. While a medical degree focusing on the relevant practice area might have been one possible avenue for gaining ordinary skill in the art at the time of the inventions, it was not the only avenue. A medical degree, without the requisite experience focusing on treatment of patients with brain disorders and experience with EEG and application of electrical or magnetic energy such as TMS, is neither necessary nor sufficient to acquire the necessary skills to be a POSITA. *Id.* ¶ 16.

V. Legal Standard for Claim Construction

It is a “bedrock principle” of patent law that the claims in a patent define the invention to which the patentee is entitled protective rights. *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312 (Fed. Cir. 2005). The purpose of claim construction is for the court to define the proper scope of the invention and to discern the meaning of the claim language the jury might otherwise misunderstand in the context of the patent and file history. *See, e.g., i2 Techs., Inc. v. Oracle Corp.*, No. 6:09-cv-194, 2011 WL 209692, *4 (E.D. Tex. Jan. 21, 2011); *Pitney Bowes, Inc. v. Hewlett-Packard Co.*, 182 F.3d 1298, 1304 (Fed. Cir. 1999). Terms or phrases in a patent claim should be given “their ordinary and customary meaning,” which is “the meaning that the term would have to [POSITA] in question at the time of the invention.” *Phillips*, 415 F.3d at 1312–13.

Where the plain and ordinary meaning of a claim term is understandable and consistent with the specification, the term requires no construction. *See, e.g., i2 Techs., Inc.*, 2011 WL 209692, at *4; *Finjan, Inc. v. Proofpoint, Inc.*, No. 13-CV-05808-HSG, 2015 WL 7770208, at *13 (N.D. Cal. Dec. 3, 2015); *Websidestory, Inc. v. Netratings, Inc.*, No. 06-CV-408 WHQ (AJB), 2007 U.S. Dist. LEXIS 50186, *31 (S.D. Cal. July 2007). *See also Phillips*, 415 F.3d at 1313 (“The ordinary meaning is that which “the term would have to a PHOSITA at the time of the invention.”). However, if such meaning is not readily apparent, the Court must look to the intrinsic evidence:

(1) the patent claims; (2) the patent specification; and (3) the prosecution history. *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 979 (Fed. Cir. 1995); *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996). “The actual words of the claim are the controlling focus.” *Digital Biometrics, Inc. v. Identix, Inc.*, 149 F.3d 1335, 1334 (Fed. Cir. 1998).

Outside of the claims themselves, the patent specification is the primary basis for construing the claims. The specification is appropriately resorted to “for the purpose of better understanding the meaning of the claim,” as the specification provides context for claim language. *Phillips*, 415 F.3d at 1315-16. *See also Phillips*, 415 F.3d at 1316 (“[T]he specification may reveal a special definition given to a claim term by the patentee that differs from the meaning it would otherwise possess. In such cases the inventor’s lexicography governs.”).

However, the claims, *not* specification embodiments, define the scope of patent protection and the *patentee is entitled to the full scope of his claims*, without being limited to only the embodiments in the specification. *See Kara Tech., Inc. v. Stamps.com, Inc.*, 582 F.3d 1341, 1348 (Fed. Cir. 2009). Unless there is a clear intention by the Applicant, the court “will not at any time import limitations from the specification into the claims,” even if only a single embodiment is described. *CollegeNet, Inc. v. ApplyYourself, Inc.*, 418 F.3d 1225, 1231 (Fed. Cir. 2005); *Liebel-Flarsheim Co. v. Medrad, Inc.*, 358 F.3d 898, 906 (Fed. Cir. 2004).

A patent’s prosecution history consists of the complete record of the proceedings before the United States Patent and Trademark Office (the “PTO”), including the prior art cited during examination of the patent. Like the patent’s specification, “the prosecution history provides evidence of how the PTO and the inventor understood the patent.” *Phillips*, 415 F.3d at 1317.

If a claim term is non-technical and derives no special meaning from the patent and its prosecution history, the Court should not function as a thesaurus. *See Brown v. 3M*, 265 F.3d 1349,

1352 (Fed. Cir. 2001). However, when a claim term is technical, the court may still provide a construction for the jury to help the jury understand complicated technical concepts. *See Control Resources, Inc. v. Delta Electronics, Inc.*, 133 F. Supp. 2d 121, 127, (D. Mass. 2001) (“In the end, claim construction must result in a phraseology that can be taught to a jury of lay people. It is not enough simply to construe the Claims so that one skilled in the art will have a definitive meaning. The Claims must be translated into plain English so that a jury will understand. Thus, accurate words that convey the essence of the invention are needed.”); *Recticel Automobilesysteme GmbH v. Automotive Components Holdings, LLC*, 2012 WL 1276003, *2 (E.D. Mich. 2012) (“A judge has two primary goals in construing the disputed claim terms. The first goal is to determine the scope of the patent by interpreting the disputed claim terms to the extent needed to resolve the dispute between the parties. The second goal is to provide a construction that will be understood by the jury who might otherwise misunderstand a claim term in the context of the patent specification and prosecution history of the patent.”); *Apple Inc. v. Motorola, Inc.*, 2012 WL 8123793, *1 (N.D. Ill. 2012) (Judge Posner sitting by designation) (instructing parties that their proposed Claim constructions had to be “in ordinary English intelligible to persons having no scientific or technical background”).

In many patent infringement lawsuits, “an analysis of the intrinsic evidence alone will resolve any ambiguity in a disputed claim term. In such circumstances, it is improper to rely on extrinsic evidence.” *Vitronics*, 90 F.3d at 1583 (Fed. Cir. 1996). However, “if after consideration of the intrinsic evidence there remains doubt as to the exact meaning of the claim terms, consideration of extrinsic evidence may be necessary to determine the proper construction.” *Digital Biometrics*, 149 F.3d at 1344. Such intrinsic evidence can include “expert testimony, dictionaries, and treatises.” *Suffolk Techs., LLC v. AOL Inc.*, 752 F.3d 1358, 1362 (Fed. Cir. 2014);

see also *Markman*, 52 F.3d at 980; *Starhome GmbH v. AT&T Mobility LLC*, 743 F.3d 849, 856 (Fed. Cir. 2014). Extrinsic evidence should always be “considered in the context of the intrinsic evidence.” *Phillips*, 415 F.3d at 1319.

A patent is only invalid for indefiniteness “if its claims, read in light of the specification delineating the patent, and the prosecution history, fail to inform, with reasonable certainty, those skilled in the art about the scope of the invention.” *Nautilus, Inc. v. Biosig Instruments, Inc.*, 572 U.S. 898, 901 (2014) (emphasis added). While purely subjective terms are indefinite, “[t]erms of degree are not ‘inherently indefinite,’ and ‘absolute or mathematical precision is not required.’” *One-E-Way, Inc. v. Int’l Trade Comm’n*, 859 F.3d 1059, 1068 (Fed. Cir. 2017) (quoting *Interval Licensing LLC v. AOL, Inc.*, 766 F.3d 1364, 1370 (Fed. Cir. 2014)). Further, just because a term is susceptible to more than one meaning does not render it indefinite: “Such a test would render nearly every claim term indefinite so long as a party could manufacture a plausible construction.” *Nevro Corp. v. Bos. Sci. Corp.*, 955 F.3d 35, 41 (Fed. Cir. 2020).

Factors in favor of finding a claim term or phrase to be definite include whether the United States Patent and Trademark Office (“PTO”) Examiner had difficulty in applying or analyzing the term during prosecution. See *Sonix Tech. Co., Ltd. v. Publications Int’l, Ltd.*, 844 F.3d 1380, 1378-81 (Fed. Cir. 2017) (reversing indefiniteness ruling and finding compelling that “the USPTO did not express any uncertainty as to the scope of ‘visually negligible,’ or encounter any apparent difficulty in applying the term to the references”); *Niazi Licensing Corp. v. St. Jude Medical S.C., Inc.*, 30 F.4th 1339, 1347 (Fed. Cir. 2022) (Federal Circuit reiterating that in *Sonix*, “[w]e also found it highly relevant that the examiner understood this phrase throughout prosecution”); *Nature Simulation Sys. v. Autodesk, Inc.*, 23 F.4th 1334, 1343 (Fed. Cir. 2022) (“[E]xaminers are deemed

to be experienced in the relevant technology as well as the statutory requirements for patentability.”).

To prevail on an indefiniteness argument, Defendant must meet the “clear and convincing evidence” standard required to invalidate a duly issued patent. *See* 35 U.S.C. §§ 112, 282 (patents are presumed valid and definite); *Sonix Tech.*, 844 F.3d at 1377 (“Indefiniteness must be proven by clear and convincing evidence.”); *Haemonetics Corp. v. Baxter Healthcare Corp.*, 607 F.3d 776, 783 (Fed. Cir. 2010) (“Because Claim construction frequently poses difficult questions over which reasonable minds may disagree, proof of indefiniteness must meet ‘an exacting standard.’”). “In some cases . . . resolution of indefiniteness as part of claim construction may be either impossible or inadvisable. Where, for example, there is a subsidiary factual issue, and the record reveals a genuine dispute of material fact, resolution may have to await further evidentiary development.” *Datacore Software Corp. v. Scale Computing, Inc.*, 2023 WL 5207928, at *5 (D. Del. Aug. 14, 2023).

VI. Agreed Constructions Reached by the Parties

The Parties have reached agreement as to the proposed constructions for eleven (11) claim terms/phrases at issue in this case. *See* Dkt. 31 at *3-5. Given the importance of these nine claim terms to the accurate and complete understanding of the subject claims in which these claim terms/phrases are found, the Parties respectfully request that the Court adopt the Parties’ agreed upon constructions for all of these claim terms/phrases.

VII. Claim Terms in Dispute

Wave will address claim term numbers 12-16 as listed in the Amended Joint Claim Construction Chart (Dkt. 31 at *6-10) in this Opening Claim Construction Brief.¹ The relevant portion of the Joint Claim Construction Chart, without intrinsic citations, is reproduced below:

No.	Claim Term/Phrase and Asserted Claims Containing Term	Plaintiff's Proposed Construction and Supporting Intrinsic Evidence	Defendant's Proposed Construction and Supporting Intrinsic Evidence
13	[A method of] improving a physiological condition or a neuropsychiatric condition '111 Patent, Claim 1	to make or become better [the medical conditions in the claim]	Indefinite and unpatentable subject matter.
14	Intrinsic frequency '490 Patent, Claim 1 '408 Patent, Claims 1-2, 12, 20 '111 Patent, Claims 3, 7 '737 Patent, Claims 1-2, 4	frequency selected to which treatment is to be applied	the frequency (f0) at which peak signal power in the specified band (Emax) is located For '111 Patent: Indefinite & Invalid: Not enabled/ lacking written description or In the alternative: "the frequency (f0) at which peak signal power in the specified band (Emax) is located"
15	In-phase/in phase '408 Patent, Claims 1, 12 '490 Patent, Claim 1	waveforms whose peaks and troughs occur at substantially the same time	waveforms whose peaks and troughs occur at the same time

¹ Per the Parties understanding of the Scheduling Order, Wave will only address claims 12-16 that it proposes need to be construed in its Opening Claim Construction Brief. Claims 12-16 include the 2 terms that both Parties agree should be construed as well as the 3 terms that only Wave proposes should be construed.

No.	Claim Term/Phrase and Asserted Claims Containing Term	Plaintiff's Proposed Construction and Supporting Intrinsic Evidence	Defendant's Proposed Construction and Supporting Intrinsic Evidence
16	Move the [Q-Factor of the] first intrinsic frequency in a pre-selected direction, up or down, within the specified EEG band using the magnetic field ² '490 Patent, Claim 1	See constructions for claim term numbers $2 + 6 + 8 + 11 + 13$	Indefinite & Invalid: Not enabled /lacking written description/failure of best mode.
17	Out of phase '408 Patent, Claims 1, 12 '490 Patent, Claim 1	waveforms whose peaks or troughs do not occur at substantially the same time	waveforms whose peaks or troughs do not occur at the same time

A. "Intrinsic Frequency"

No.	Claim Term/Phrase and Asserted Claims Containing Term	Plaintiff's Proposed Construction and Supporting Intrinsic Evidence	Defendant's Proposed Construction and Supporting Intrinsic Evidence
14	Intrinsic frequency '490 Patent, Claim 1 '408 Patent, Claims 1-2, 12, 20 '111 Patent, Claims 3, 7 '737 Patent, Claims 1-2, 4	frequency selected to which treatment is to be applied	the frequency (f ₀) at which peak signal power in the specified band (E _{max}) is located For '111 Patent: Indefinite & Invalid: Not enabled/lacking written description

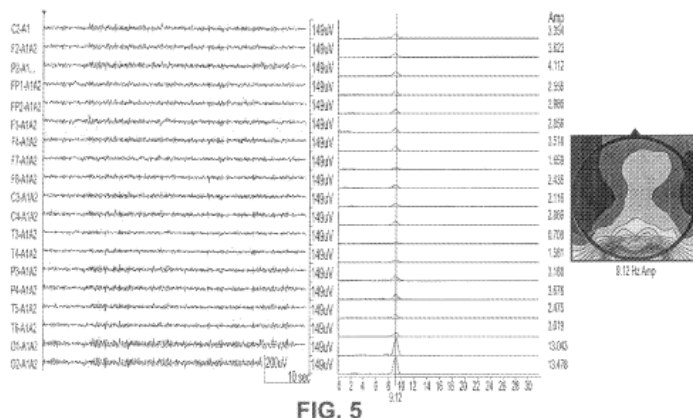
As noted above, the claim term "intrinsic frequency" is used in certain asserted claims of each of the Asserted Patents. Wave's proposed construction of the term "intrinsic frequency" as "frequency selected to which treatment is to be applied"³ is consistent with and fully supported by the intrinsic evidence of each of the Asserted Patents. Throughout the specifications of the

² As this claim term is a combination of other claim terms either agreed to or proposed for construction, Wave incorporates its arguments as to each of these claim terms in its brief.

³ The parties separately propose to construe "pre-selected intrinsic frequency". See *supra* at *10.

Asserted Patents, “intrinsic frequency” is disclosed as the identified or specified brain biometric marker (“biomarker”) of the subject (i.e. patient receiving treatment) that will be adjusted, shifted, or otherwise moved during treatment. Some of the many supporting examples are included below (emphasis added):

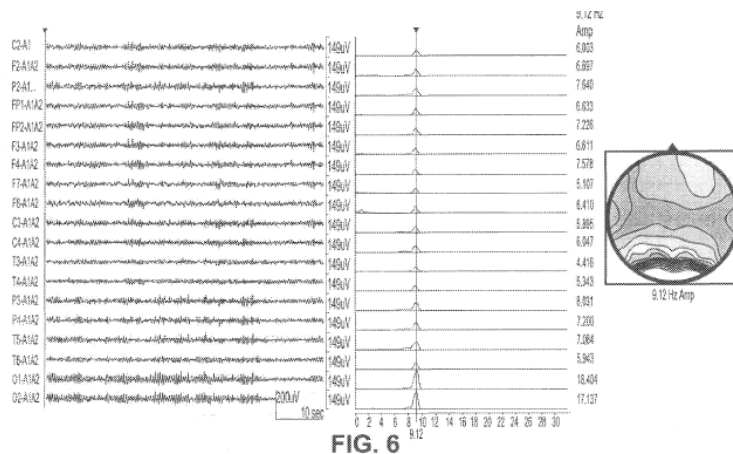
- “In another aspect are devices comprising a means for applying a magnetic field to a head of a subject; whereby the means for applying the magnetic field is capable of **influencing an intrinsic frequency** of a brain of the subject within a specified EGG band.” Dkt. 29-3, ’408 Patent at 7:12-16; Bikson Dec. ¶ 63.
- “FIG. 5 shows a sample EEG segment for a subject before therapy is delivered. The block on the left shows a time series EEG while the subject is sitting at rest with eyes closed. The block in the center shows the energy across the frequency spectrum for the sampled EEG. The vertical line drawn through the peaks is at 9.1 Hz, the **subject's intrinsic alpha frequency**. The circle at the right shows the distribution of EEG energy at the intrinsic alpha frequency throughout the scalp, looking down on the top of the subject's head. In the circle representation, the majority of the EEG energy at the **[intrinsic] alpha frequency**⁴ is concentrated at the back of the brain.” ’408 Patent, 15:5-15; Bikson Dec. ¶ 65.



- “FIG. 6 is similar to FIG. 5, except the EEG was sampled immediately following therapy. In this, it can be seen that the energy associated with the **intrinsic alpha frequency** has increased significantly. From the circle representation on the right, it can be seen that the distribution of energy at the **intrinsic alpha frequency**

⁴⁴ The inclusion of the word “alpha” within “intrinsic alpha frequency” simply refers to a subject’s intrinsic frequency with the selected alpha band. Brainwaves are organized into different frequency “ranges” or “bands”, as measured by an EEG, using Greek numerals. The most commonly studied waveforms include delta (0.5 to 4Hz); theta (4 to 7Hz); alpha (8 to 12Hz); sigma (12 to 16Hz) and beta (13 to 30Hz). <https://www.ncbi.nlm.nih.gov/>. See also Bikson Dec. ¶ 66.

throughout the head is more uniform, though the majority of energy is still concentrated at the back of the brain.” ’408 Patent, 15:16-23. *See also* Bikson Dec. ¶ 67.



- “In another aspect are methods of using a Transcranial Magnetic Stimulation (TMS) device for **influencing an intrinsic frequency** of a subject within a specified EEG band, comprising: (a) adjusting output of said TMS device; (b) **changing** EEG frequency, Q-factor, or coherence by repetitive firing of a magnetic field using said TMS device; and (c) applying said magnetic field close to a head of the subject.” ’490 Patent, 7:4-10. *See also* ’737 Patent 7:1-7. *See also* Bikson Dec. ¶ 68.
- “Various bodily functions operate at frequencies that are harmonics or sub-harmonics of the brain's **intrinsic frequency**.” ’111 Patent, 2:39-41. *See also* Bikson Dec. ¶ 76.
- “Further, Claim 2 of the present invention recites adjusting output of a magnetic field and influencing the subject's **intrinsic frequency** in a specified EEG band toward a pre-selected intrinsic frequency of *the same* EEG band. On the other hand, Katz's only intention and goal is to move a subject *from a current brain state into a desired brain state*. Since the brain states correlate to separate EEG bands in Katz (i.e. from relaxed in the alpha band to sleep in the delta or theta band), *Katz' methods and devices move the brain waves from one band to another.*” ’408 Prosecution History at *800 (September 10, 2012 Amendment in Response to Final Office Action, p. 8) (italics in original). *See also* Bikson Dec. ¶ 78.
- “In regards to claims 1 and 2, the prior art of record does not teach or suggest a method as claimed by Applicant, that includes the step of moving at least one of an **intrinsic frequency** of a specified EEG band of the subject toward a pre-selected intrinsic frequency of the specified EEG band and a Q-factor of an intrinsic frequency within a specified EEG band of the subject toward a pre-

selected O-factor using said magnetic field.” ’737 Prosecution History at *1508 (March 25, 2014, Final Office Action, p. 5). *See also* Bikson Dec. ¶ 79.

See also Bikson Dec. ¶¶ 64, 69-77, 80 (additional examples).

When “an analysis of the intrinsic evidence alone will resolve any ambiguity in a disputed claim term” intrinsic evidence alone, not extrinsic evidence, should be used to determine claim construction. *See Vitronics*, 90 F.3d at 1583. Here, the intrinsic evidence clearly and repeatedly supports Wave’s proposed construction of “intrinsic frequency” as the “frequency selected to which treatment is to be applied”. As noted above, the intrinsic evidence is replete with examples of the claim term “intrinsic frequency” being associated with the subject to which treatment is being applied by such intrinsic frequency being moved, influenced, altered, or shifted to a different frequency. This proposed construction also aligns with the claims themselves. For example, Claim 2 of the ’408 Patent covers “a method of treating . . . comprising moving at least one of: an intrinsic frequency of a brain of the subject within a specified EEG band toward a pre-selected intrinsic frequency within the same specified EEG band.” Dkt. 029-03 66:54-56; Bikson Dec. ¶ 62. Thus, it is clear that “intrinsic frequency” is the subject’s biometric marker that will be moved as a result of the treatment.

In contrast, Defendant’s proposed construction, i.e. “the frequency (f_0) at which peak signal power in the specified band (E_{max}) is located” violates a fundamental principle of claim construction by improperly importing a specific embodiment into the claim. Case law is clear that, absent a clear intention by the Applicant, courts “*will not at any time* import limitations from the specification into the claims”. *See CollegeNet, Inc. v. ApplyYourself, Inc.*, 418 F.3d 1225, 1231 (Fed. Cir. 2005) (emphasis added). Defendant not only fails to identify any such clear intent by Wave to import any such limitations into any of the applicable claims; Defendant makes no attempt

to do so. This alone is sufficient for the Court to reject Defendant’s proposed construction of this claim term.

In addition, rather than propose a construction supported by the intrinsic evidence, Defendant’s proposed construction is inexplicably derived, at least in part, from the description of Fig. 12 of the ’408, ’737, and ’490 Patents, which is directed to a separate claim element; namely, “Q-Factor” and *not* “intrinsic frequency”. See Dkt. 029-03, ’408 Patent at 15:49-59; Bikson Dec.

¶ 82. As shown below, Figure 12 explains how to calculate the Q-Factor.

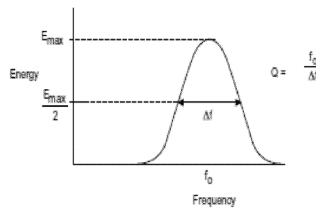


Figure 12

See also Bikson Dec. ¶ 83. This calculation of Q-Factor ($Q = f_0/\Delta f$) relies on the term “ f_0 ” which is defined to be the “intrinsic frequency in the specified band”. Dkt. 029-03, ’408 Patent at 15:54-55; Bikson Dec. ¶ 84. Defendant then uses other terms related to this Q-Factor calculation to complete its proposed construction of “intrinsic frequency”. *Id.* As noted by Dr. Bikson (Wave’s technical expert), Defendant’s proposed construction is not only mathematically incorrect, it is not supported by the intrinsic evidence of any of the Asserted Patents. See Bikson Dec. ¶¶ 85-87.

In addition, Defendant’s proposed construction does nothing to help either this Court or a jury to decipher what the meaning of intrinsic frequency — a prime purpose of claim construction. See *Control Resources*, 133 F. Supp. 2d at 127; *Recticel Automobilesysteme GmbH*, 2012 WL 1276003 at *2; *Apple Inc.*, 2012 WL 8123793 at *1. By comparison, Wave’s construction does not improperly import an embodiment or limitation from the specification to the Claims, is phrased in plain English to assist the Court and a jury to understand the meaning of the Claim term

“intrinsic frequency”, and is consistent with and fully supported by the intrinsic evidence of each of the Asserted Patents. For all of these reasons, Wave requests that this Court adopt “frequency selected to which treatment is to be applied” as the proper construction of the claim term “intrinsic frequency”.

B. “In-Phase” and “Out of Phase”

The related terms “in-phase” and “out of phase” are used in Claims 1 and 12 of the ’408 Patent and Claim 1 of the ’490 Patent in relation to the concept of the EEG phase.

No.	Claim Term/Phrase and Asserted Claims Containing Term	Plaintiff’s Proposed Construction and Supporting Intrinsic Evidence	Defendant’s Proposed Construction and Supporting Intrinsic Evidence
14	In-phase/in phase ’408 Patent, Claims 1, 12 ’490 Patent, Claim 1	waveforms whose peaks and troughs occur at substantially the same time	waveforms whose peaks and troughs occur at the same time
16	Out of phase ’408 Patent, Claims 1, 12 ’490 Patent, Claim 1	waveforms whose peaks or troughs do not occur at substantially the same time	waveforms whose peaks or troughs do not occur at the same time

As highlighted in the table above, the only difference between Wave’s proposed construction and that of Defendant is whether the timing of these waveforms must be at exactly the same or substantially the same time.

When a claim term is non-technical and derives no special meaning from the patent and its prosecution history, the Court should not function as a thesaurus. *See Brown*, 265 F.3d at 1352. However, when a claim term is technical, the Court may still provide a construction for the jury to help the jury understand complicated technical concepts. *See Control Resources*, 133 F. Supp. 2d at 127; *Recticel Automobilesysteme GmbH*, 2012 WL 1276003 at *2; *Apple Inc.*, 2012 WL

8123793 at *1. Here, construction of the technical terms “in-phase” and “out of phase” will help the jury understand the concept of the EEG phase.

Importantly, during claim construction negotiations, the Parties agreed to a proposed construction of “EEG Phase” as “a measure that conveys the difference, if any, between the timing of peaks and/or troughs in two EEG signals”. *See* Dkt. 29 at *5. This agreed construction includes the phrase “timing of peaks and/or troughs”.

Wave did not act as its own lexicographer and did not alter the plain and ordinary meaning that a POSTIA would have of the claim terms “in-phase” and “out of phase”. *See Phillips*, 415 F.3d at 1316. As such, extrinsic evidence is both relevant to and necessary to understand the “in-phase” and “out of phase” terms. *See Digital Biometrics*, 149 F.3d at 1344.

The dispute regarding these two claim terms centers around whether the peaks and troughs of a waveform must occur at exactly the same time to be in-phase. Defendant contends that it does, while Wave contends the timing must be “substantially” the same. As detailed in Dr. Bikson’s Declaration, a POSITA would understand that the timing need only be “substantially the same” because small differences in phase do not lead to large differences in results.⁵ Bikson Dec. ¶ 96. In practice, small differences in phase can accumulate over many cycles. *Id.* ¶ 97. But such small differences do not render a waveform out of phase. *Id.*

This analysis is further supported by the intrinsic evidence of the ’408 and ’490 Patents. Specifically, the specification of each of these patents provides for similar flexibility of timing: “[t]he tensioner assemblies in the embodiments shown in FIG. 17, FIG. 18, and FIG. 19, for non-limiting example, are configured to keep the drive belts taut during use and, therefore, ensure that the rotation of the magnets is simultaneous and **generally in-phase** as applied to the subject where

⁵ Dr. Bikson provides a detailed example to further support this statement. *See* Bikson Dec. ¶¶ 92-96.

the magnets are aligned such that each of the neutral planes of each of the three magnets are generally aligned to be parallel to the scalp of the subject.” Dkt. 029-03, ’408 Patent, 55:42-49. *See also* Dkt. 029-04, 490 Patent, 73:4-11; Bikson Dec. ¶ 98. Defendant’s proposed construction is too exacting and runs afoul of the intrinsic evidence in violation of controlling law. *See Phillips*, 415 F.3d at 1319 (noting that extrinsic evidence must be “considered in the context of the intrinsic evidence”). As such, Defendant’s proposed construction should not be adopted. *See also* Bikson Dec. ¶¶ 99, 102.

Defendant’s position is also notably contrary to its position with respect to other agreed upon claim term constructions. For instance, Defendant agreed with Wave’s proposed construction of the claim term “to a target” as “to be substantially the same as a target”. *See* Dkt. 31 at *4. Thus, Defendant previously conceded the requisite level of precision of the word “substantially” as applied to other claim terms, including other claim terms used in Claim 12 of the ’408 Patent. As such, Defendant should be precluded from contesting Wave’s proposed construction of this claim term to the extent that it is grounded on any opposition to the use of the word “substantially.” For all of the above reasons, the Court should adopt Wave’s proposed constructions for “in-phase” and “out of phase”.

C. “Improving a physiological condition or a neuropsychiatric condition”

No.	Claim Term/Phrase and Asserted Claims Containing Term	Plaintiff’s Proposed Construction and Supporting Intrinsic Evidence	Defendant’s Proposed Construction and Supporting Intrinsic Evidence
10	[A method of] improving a physiological condition or a neuropsychiatric condition ’111 Patent, Claim 1	to make or become better [the medical conditions in the claim]	Indefinite and unpatentable subject matter.

The phrase “improving a physiological condition or a neuropsychiatric condition” appears in Claim 1 of the ’111 Patent. *See* Dkt. 029-02 at 7:54-55. Defendant fails to propose any construction for this claim term and, instead, incorrectly asserts that a slightly longer version of this claim term, “a method of improving a physiological condition or a neuropsychiatric condition”, is indefinite and constitutes unpatentable subject matter. Wave intends to establish that this claim term as it appears in Claim 1 of the ’111 Patent is clearly understood by a POSITA and is not indefinite in its forthcoming Opposition to Defendant’s Opening Claim Construction brief.⁶

Notably, after full briefing by the Parties, the Court in the co-pending, PeakLogic Case⁷ construed the word “improves” as appearing in U.S. Patent No. 9,446,259, entitled, “Systems and Methods for Neuro-EEG Synchronization Therapy” (the “’259 Patent”), to mean “to make or become better [the medical conditions in the claims]”. *See* Taché Dec. Ex. C at *2. While the ’111 Patent and the ’259 Patent use different biological metrics to generate the specific TMS treatment plans, both patents are: (i) related to improvements in TMS therapy; (ii) have one of the named co-inventors in common; and (iii) are both owned by Wave. *See* Bikson Dec. ¶ 26. Consequently, the term “improves” as it appears here in the ’111 Patent should be construed consistently with the construction adopted by the Court in the ’259 Patent. *See NTP, Inc. v. Research In Motion, Ltd.*, 418 F.3d 1282, 1293 (Fed. Cir. 2005) (“Because [plaintiff’s] patents all derive from the same parent application and share many common terms, we must interpret the Claims consistently across all asserted patents . . . We thus draw distinctions between the various patents only where necessary.”); *Capital Mach. Co. v. Miller Veneers, Inc.*, 524 F. App’x. 644, 647 (Fed. Cir. 2014)

⁶ Pursuant to the agreement of the Parties, Wave will limit its arguments contained in this brief to establishing that its proposed construction of this claim term is not only properly supported by the intrinsic evidence, but is consistent with the a POSITA’s understanding of this claim term and that the proposed construction meets the objectives of providing an understanding to this Court and a jury.

⁷ Case No. 3:21-cv-01330 (S.D. Cal.).

(explaining that claims term in related patents should be construed consistently across related patents).

Claim 1 of the '111 Patent describes a “method of improving a physiological condition or a neuropsychiatric condition of a mammal” by subjecting the mammal (i.e. human) to rTMS at a frequency of a non-EEG biological metric or a harmonic or sub-harmonic of the same. *See* Dkt. 029-02 7:54-59. Physiological or neuropsychiatric conditions are associated with a number of clinical symptoms. Claim 1 uses the term “improving” to describe the clinical purpose of making the symptoms associated with these classes of disorders better, and clinicians know how to evaluate patient symptoms and whether they have been reduced. Bikson Dec. ¶¶ 24-25, 27.

Courts have construed and held definite, terms of comparison like “improving”, including in the clinical context where individuals, with their individual characteristics, are being treated to make symptoms better. *See, e.g., Salix Pharms., Ltd. v. Norwich Pharms., Inc.*, No. 20-430-RGA, 2022 U.S. Dist. LEXIS 142335, *66-67 [2022 WL 3225381] (Aug. 10, 2022 D. Del.) (Andrews, J.) (trial opinion) (holding term definite and crediting expert testimony that “**adequate relief of symptoms** is used to determine IBS-D treatment success in the field,” even as to “a collection of symptoms [where] there is no biomarker to determine a successful overall treatment”); *Invitrogen Corp. v. Biocrest Mfg., L.P.*, 327 F.3d 1364, 1369 (Fed. Cir. 2003) (affirming construction of term “**improved** competence” as “generally increased” without any specific numerical limitation); *U.S. Silica Co. v. Amberger Kaolinwerke Eduard Kick GmbH*, No. 2:20-CV-00298- JRG, p. 22 (E.D. Tex. Nov. 19, 2021) (Gilstrap, J.) (“**improves** adherence” not indefinite as “a skilled artisan would understand that improvement to be relative to the adherence of the particles to the asphalt layer without any treatment”); *Continental Ag v. Gates Corp.*, No. IPR2021-00466, 2022 WL 3012945, at *4 (P.T.A.B. July 29, 2022) (citing Merriam Webster dictionary) (USPTO noting that the

“meaning of ‘**improved**’ is well understood. For example, and although we acknowledge that it is extrinsic evidence, the word ‘improved,’ means to ‘make better.’”).

A POSITA would understand that the claimed invention is directed to treating physiological and neuropsychiatric conditions, and that “improving” is used in its plain and ordinary sense of “to make or become better” with the physiological and neuropsychiatric conditions. Bikson Dec. ¶¶ 51-54. Claim terms are to be understood in context, and, here, the specification of the ’111 Patent teaches “improving” in the context of treating patients who are suffering from clinically assessed mental disorders, so as to make their symptoms associated with these conditions better. The ’111 Patent specification also describes treatment using the patented inventions in terms of improving or reducing the symptoms the patients suffer due to their conditions. Some of these teachings are recited below (with emphasis added as needed):

- “Transcranial magnetic stimulation and rTMS have been used to **treat** many psychological and medical disorders such as major depressive disorder, Parkinson's disease, Alzheimer's disease, autism spectrum disorder (ASD), schizophrenia and others.” Dkt. 029-02, ’111 Patent, 1:24-28. *See* Bikson Dec. ¶ 33.
- “By modulating the brain activity of a mammal, **improvements** in physical conditions, psychological conditions, and neuropsychiatric conditions are **improved** in a non-invasive manner and usually without the need for medications.” Dkt. 029-02, ’111 Patent, 1:59-62. *See also* Bikson Dec. ¶ 35.
- “Alpha band is normally found during periods of relaxation while closing the eyes. Physiologically it is associated with the process of inhibition control. Lack of alpha activity is found in autism, and other mental disorders, such as anxiety, schizophrenia, and ADHD. Reduced alpha frequency coherence has been found in patients with Alzheimer's disease. Excessive alpha activity may be seen in comatose conditions. In general, rTMS in this range will help **treat** autism, reduce anxiety, increase attention, or treat schizophrenia and Alzheimer's.” Dkt. 029-02, ’111 Patent, 4:1-11. *See also* Bikson Dec. ¶ 37.
- “Beta band is associated with alertness, busy or anxious thinking. Significant reduction of beta activity is often found in subjects treated with benzodiazepines. rTMS in this range will help to **increase** alertness.” Dkt. 029-02, ’111 Patent, 4:13-17. *See* Bikson Dec. ¶ 38.

- “Gamma activity displays during cross-modal sensory processing or short term memory matching of recognized objects, sounds, or tactile sensations. A decrease in gamma band activity may be associated with cognitive decline, such as Alzheimer's disease. rTMS in this range is used to **treat** cognitive deficits in Alzheimer's disease or other forms of dementia.” Dkt. 029-02, ’111 Patent, 4:18-26. *See* Bikson Dec. ¶ 39.

See also Bikson Dec. ¶¶ 34, 36 (additional examples).

The term “improving” does not call for any purely subjective inquiry as Defendant will likely assert, but, instead, relies on a clinical assessment that provides a baseline against which the treatment’s effectiveness in reducing the patient’s symptoms for the conditions can be measured after treatment. Bikson Dec. ¶ 40. Indeed, the ’111 Patent specification gives a number of examples of clinical assessments used to measure such improvement as shown below (emphasis added in bold as needed):

- The specification in “Example 1” describes treatment of autism in a 9-year old boy wherein the boy was treated with rTMS to adjust his alpha frequency: “Single-lead ECG showed a regular heartbeat at 1.5 Hz. Taking its 6th higher harmonic, it was decided to set the rTMS at 9.0 Hz over the mid-central and left frontal lobe. Following the first 2 sessions of rTMS, the patient showed some degree of improvement with more vigilance and spontaneous communication. With further treatments there was a significant reduction of the slow waves in the patient's EEG and an increase in alpha rhythm. Clinically, the frequency of seizure episodes reduced significantly. After titrating down the anticonvulsant dosage over time, the patient experienced a significant improvement in cognitive and motor functions.” Dkt. 029-02, ’111 Patent 7:1-12. *See* Bikson Dec. ¶ 41.
- The specification in “Example 2” describes treatment and pain management in an adult male after suffering for years after multiple back surgeries: “Single-lead ECG showed a regular heartbeat at 1 Hz. Taking its 9th higher harmonic, it was decided to set the rTMS at 9 Hz over the bilateral pre-frontal lobe. Following 3 sessions of rTMS, the patient showed a significant reduction in pain. The EEG pattern showed significant improvement in alpha synchronization.” Dkt. 029-02, ’111 Patent, 7:21-26. *See* Bikson Dec. ¶ 42.
- The specification in “Example 3” describes treatment of an 85-year old adult female who had been diagnosed with Alzheimer’s Disease 15 years prior to treatment and who was suffering memory loss: “The patient's EEG showed alpha peak frequency below 8 Hz which is in the theta band range. Single-lead ECG showed a regular heartbeat at 1.2 Hz. Taking its 7th higher harmonic, it was decided to set the rTMS

at 8.4 Hz over the bilateral pre-frontal lobe. Following 1 session of rTMS, the patient showed a significant improvement in short term memory and working memory. After 2 weeks of daily (Monday-Friday) rTMS sessions the patient became more coherent and her MMSE score improved from 14 pre-treatment to 21 post treatment. The EEG pattern showed an alpha wave near 8 Hz.” Dkt. 029-02, ’111 Patent, 7:35-43. *See* Bikson Dec. ¶ 43.

Thus, a POSITA would understand that the claims of the ’111 Patent use the term “improving” to describe the clinical purpose of making better the symptoms associated with the physiological and neuropsychiatric conditions, and would know how to evaluate whether symptoms have been made better after treatment. Bikson Dec. ¶¶ 50-52.

The prosecution history of the ’111 Patent further establishes that the term “improving” is definite, because the Examiner had no difficulty in determining the scope of “improving” and was able to understand and apply the term in performing prior art searches and in making rejections from the perspective of what would have been obvious to a POSITA. *See* Bikson Dec. ¶¶ 48-49; *Sonix Tech.*, 844 F.3d at 1379-81; *Niazi Licensing*, 30 F.4th at 1347; *Nature Simulation*, 23 F.4th at 1343.

As detailed above, the intrinsic evidence clearly and substantially supports Wave’s proposed construction of the “improving” phrase and, thus, extrinsic evidence is not necessary for the Court to construe the phrase. *See Vitronics*, 90 F.3d at 1583 (Fed. Cir. 1996). Nevertheless, the extrinsic evidence also supports Wave’s construction. *See Digital Biometrics*, 149 F.3d at 1344. Extrinsic evidence may be in the form of dictionary definitions. *See Suffolk Techs.*, 752 F.3d at 1361 (Fed. Cir. 2014). The Merriam-Webster dictionary defines “improve” as “make better”. Bikson Dec. ¶ 53. Similarly, the Medical Dictionary for the Health Professions and Nursing defines improvement as “the act or process of making better”. *Id.* ¶ 54. Both definitions are consistent with Wave’s proposed construction.

Finally, Defendant's use of "improving" is also instructive in determining whether the claim language has discernible meaning and is, therefore, definite. Defendant's website (www.brainfrequency.ai) repeatedly uses the term "improving" consistent with Wave's proposed construction in this case (emphasis added):

- "The Brain Frequency™ AI system is an innovative therapeutic approach to **improving** brain health and wellness." Tache Dec., Ex. B at *2; Bikson Dec. ¶ 55.
- "TMS treatment has traditionally been used to manage depression. However, TMS therapy does not use qEEG to tailor **treatment** plans to individual needs. Brain Frequency™ is an individualized approach to TMS and is more effective as each patient's brain has a unique frequency needed for optimal performance. Brain Frequency™ has dramatically **improved** the **treatment** of patients with major depressive disorders, post-traumatic stress, TBI, anxiety, addictive disorders, ADHD, sleep disorders, and OCD." Tache Dec., Ex. B at *7; Bikson Dec. ¶ 56.

Such references to "improving" appearing on Defendant's own website today are instructive of the fact that Defendant and researchers, like a POSITA and a lay person, clearly understand the meaning of the term "improving" in the context of the technology disclosed and claimed in the '111 Patent. *See also* Bikson Dec. ¶ 57.

While Wave understands that Defendant's primary objection is to the "improving" portion of the claim phrase, not the "physiological condition or a neuropsychiatric condition" portion, the latter portion is also definite and supported by the intrinsic evidence. The specification clearly defines what a "neuropsychiatric condition" that can be improved would include: "symptoms of Autism Spectrum Disorder (ASD), Alzheimer's disease, attention deficit hyperactivity disorder (ADHD), schizophrenia, anxiety, depression, coma, Parkinson's disease, substance abuse, bipolar disorder, a sleep disorder, an eating disorder, tinnitus, traumatic brain injury, post traumatic stress disorder (PTSD), or fibromyalgia." Dkt. 029-02, '111 Patent, 2:1-8; Bikson Dec. ¶ 36. This is further confirmed by dependent Claim 6, which incorporates the limitations of Claim 1. Dkt. 029-02, '111 Patent, 8:12-17; Bikson Dec. ¶ 46. *See also Wright Medical Technology, Inc. v. Osteonics*

Corp., 122 F.3d 1440, 1445 (Fed. Cir. 1997) (“we must not interpret an independent claim in a way that is inconsistent with a claim which depends from it”). Similarly, dependent Claim 5 explains that the “physiological conditions” which can be improved include: “concentration, sleep, alertness, memory, blood pressure, stress, libido, speech, motor function, physical performance, cognitive function, intelligence, height or weight”. Dkt. 029-02, ’111 Patent at 8:7-11; Bikson Dec. ¶ 45. Thus, the “physiological condition or a neuropsychiatric condition” portion of the disputed phrase is also definite and clearly supported by intrinsic evidence in the ’111 Patent specification.

Because the intrinsic evidence clearly establishes that the phrase “improving a physiological condition or neuropsychiatric condition” is definite and used according to its plain and ordinary meaning, the Court should construe “improving a physiological condition or a neuropsychiatric condition” to mean “to make or become better [the medical conditions in the Claim]” as proposed by Wave and in line with the Claim Construction Order from the PeakLogic Court.

VIII. Conclusion

For all of the above reasons, Wave respectfully requests the Court adopt Wave’s proposed claim constructions.

DATED: May 17, 2024

Respectfully submitted,

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CERTIFICATE OF SERVICE

The undersigned hereby certifies that counsel of record who are deemed to have consented to electronic services are being served with a copy of this document via the Court's CM/ECF system per Local Rule CV-5(a) on May 17, 2024.

/s/ J. Rick Taché

J. Rick Taché